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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,006	06/22/2006	Jaap Van Der Louw	2003.810US	8561
67706	7590	01/06/2009	EXAMINER	
ORGANON USA, INC. c/o Schering-Plough Corporation 2000 Galloping Hill Road Mail Stop: K-6-1, 1990 Kenilworth, NJ 07033			ZAREK, PAUL E	
			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
			01/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/584,006	Applicant(s) VAN DER LOUW ET AL.	
	Examiner Paul Zarek	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4,6 and 10-16 is/are allowed.
- 6) ☒ Claim(s) 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/12/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 5, 7, and 9 have been cancelled, Claims 2, 3, 6, 8 were amended and Claims 10-16 were added by the Applicant in correspondence filed on 06/22/2006. Claims 1- are currently pending. This is the first Office Action on the merits of the claim(s).

Election/Restrictions

2. Applicant's election with traverse of Group I, drawn to a compound of formula I, with (7a,17ab)-17a-hydroxy-7,17-dimethyl-D-homoeestr-4-en-3-one in the reply filed on 09/09/2008 is acknowledged. The traversal is on the ground(s) that Ananchencko, et al., did not teach an embodiment of a compound of formula I, and thus the invention maintains a special technical feature. Examiner finds this argument persuasive and the requirement for restriction and election of species is vacated.
3. Claims 1-3, 4, 6, 8, and 10-16 are examined.

Priority

4. Applicant's claim for the benefit of a prior-filed international application PCT/EP04/53475 (filed on 12/15/2004) under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The effective filing date of the instant application is 12/15/2004.

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5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to European application 03104898.6 (filed on 12/22/2003). The date of foreign priority of the instant application is 12/22/2003.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim element "A kit for male contraception comprising means for the administration. . ." is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The instant specification provides no support for a kit comprising the means for administration of any drug. It is unclear how the invention is providing a method by which the progestagen and/or androgen is administered.

Applicant is required to:

- (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or
- (b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

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If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

- (a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or
- (b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Prior art

8. The prior art does not teach or make obvious the claimed compounds. As shown by the instant specification, the claimed compounds have high androgenic and prostagenic potency (Table 1), are bioavailable (Table 1), and are not toxic to the liver (Table 3). The closest prior art is Ananchenko, et al. (Tetrahedron, 1962, provided in IDS), or Sokolowski, (US Patent No. 4,412,993, 1983).

9. Claims 1-4, 6, and 10-14 are drawn to a compound of formula I or a pharmaceutical formulation of formula I. Ananchenko, et al., teach a compound similar to the claimed invention (pg 1359, Compound XXVII). The only difference is that compound XXVII lacks a

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methyl group at the 7 position. The compound taught by Ananchenko, et al., is used as reference compound A in Table 1. Applicant demonstrates that the presence of the methyl group at the 7 position dramatically increases the oral bioavailability of the claimed compound over the reference compound. Moreover, Ananchenko, et al., do not disclose the androgenic or progestational activity of compound XXVII.

10. Sokolowski teaches the steroid (7a,17b)-17-hydroxy-7,17-dimethylestr-4-en-3-one, or mibolerone (col 2, lines 60-67). The difference between the claimed compound and mibolerone is that mibolerone contains a cyclophenyl group, while the claimed compounds contain only cyclohexyl groups. Applicants also demonstrate that mibolerone, while highly orally bioavailable, has significantly higher liver toxicity than the claim compounds.

11. Claim 15 is drawn to a method of contraception in a male patient comprising administration the claimed compound, which has both androgenic and progestational activity. Anawalt and Amory teach that the best hope for a male contraceptive lies in a therapy that combines both an androgen and a progestin (pg 1396, "Expert Opinion).

12. Claim 16 is drawn to a method of treating androgen insufficiency comprising administration to a male the claimed compound. Snyder (Chapter 59, Androgens, Goodman & Gilman's The Pharmacological Basis of Therapeutics, 10th ed., 2001) teach that "the clearest indication for administration of androgens is testosterone deficiency" (pg 1643, "Therapeutic Uses of Androgens"). Testosterone deficiency is a form of androgen insufficiency.

Conclusion

13. Claims 1-4, 6, and 10-14 are currently allowable.

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14. Claim 8 is rejected.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625